

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1, 4, 6, 7, 10, 11, 14, 15, 17-26, and 28-30 are pending in the present application. Claims 6, 14, 15, and 18 have been amended. Support for amended claim 6 may be found in the present specification at page 5, lines 5-15. Claims 14 and 15 have been amended to address the formal matters raised in the outstanding Official Action. Support for amended claim 18 may be found in claim 1. Claims 28-30 have been added. Support for claims 28-30 may be found in original claims 1, 18 and 4.

In the outstanding Official Action, claims 1, 4, 6, 7, 10, 11, 14, 15, and 17-26 were rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the written description requirement. This rejection is respectfully traversed.

In imposing the rejection, the Official Action alleges that the present disclosure does not describe the common attributes or characteristics that identify members of the genus. Moreover, the Official Action characterizes the genus as "highly variant".

However, applicant notes that claims 18-21 and 28-30 are directed to a protein consisting of amino acids 1-83 of SEQ ID NO. 2. As the present application plainly shows that the

applicant was in possession of a peptide consisting of amino acids 1-83 of SEQ ID NO. 2, applicant believes that claims 18-21 and 28-30 satisfy the written description requirement.

As to the remaining claims, the Examiner is respectfully reminded that whenever the issue arises as to written description, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

Upon reviewing the present application, applicant notes that the present specification discloses peptides containing amino acids 1-83 of SEQ ID NO. 2. Moreover, the present specification teaches that these peptides are directed to isolated mite-derived proteins which may act as antigens derived from the mite *Sarcoptes scabiei*. As a result, applicant believes that the present disclosure provides sufficient identifying characteristics that indicate that the applicant was in possession of the claimed invention at the time the application was filed.

At this time applicant also notes that an error in the sequence listing has been detected. A sequence listing mistake was made when the Swedish application was proceeded with as a PCT application. Upon reviewing the Swedish priority application, it is apparent that applicant was in possession of the entire protein at the time the application was filed. A copy is enclosed for the Examiner's convenience. In the Swedish priority application (SE-9900674-4), which resulted in a granted patent (SE-C2-515819), the correct sequence listing was included, but was not included in the filed PCT application. Both sequence listings refer to three sequences that refer to the protein/DNA of the present application. However, the sequences of the present sequence listing are shorter than the correct sequence listing. In the Swedish priority application sequence listing SEQ ID NO:1 refers to an amino acid sequence of 770 amino acids

and a nucleotide sequence of 3345 nucleotides, SEQ ID NO:2 refers to an amino acid sequence of 770 amino acids (the same as in SEQ ID NO:1) and SEQ ID NO: 3 refers to an amino acid sequence of 83 amino acids. In contrast, in the present sequence listing SEQ ID NO:1 refers to an amino acid sequence of 427 amino acids and a nucleotide sequence of 1284 nucleotides, SEQ ID NO:2 refers to an amino acid sequence of 427 amino acids (the same as in SEQ ID NO:1) and SEQ ID NO:3 refers to an amino acid sequence of 12 amino acids. In the present claim 1, it is referred to 83 amino acids of SEQ ID NO:2. As referred to in the description at page 10, lines 1-3, a preferred amino acid sequence of the present invention has the length of 83 amino acids. Also, as referred to on page 15, lines 12-15 and claim 5, a preferred nucleotide sequence of the present invention is substantially identical to bases no. 1030-1279 of SEQ ID NO:1 (i.e. corresponding to 83 amino acids).

In view of the above, applicant believes that it is apparent that applicant was in possession of the entire protein at the time the application was filed.

Thus, in view of the above, applicant respectfully requests that the rejection be withdrawn.

Claims 20-21 were rejected under 35 USC 112, first paragraph, for allegedly not satisfying the enablement requirement. Applicant believes that the present amendment obviates this rejection.

As noted above, claims 18-21 and 28-30 recite peptides that consist of SEQ ID NO. 2. As a result, applicant believes that the above-identified rejection has been obviated.

In the outstanding Official Action, claim 6 was rejected under 35 USC 102(b) as allegedly being anticipated by BIRKETT et al. This rejection is respectfully traversed. Claim 6 has been amended to recite an isolated nucleic acid that encodes for a mite protein antigen. Applicant believes that BIRKETT et al. fail to disclose or suggest such a recitation. As a result, applicant believes that BIRKETT et al. fail to anticipate the claimed invention.

Claims 14-15 were rejected under 35 USC 102(e) as allegedly being anticipated by HSU. However, the proteins of HSU are not related to the proteins of the present application. Applicant notes that major differences between CAIP and the proteins of the present application exist. As a result, applicant believe that HSU fails to disclose or suggest a method for screening a protein for treating a disease associated with mites. As a result, applicant respectfully requests that the rejection be withdrawn.

Claims 14-15 were rejected under 35 USC 112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant believes that the present amendment obviates this rejection.

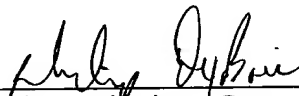
In amending claims 14 and 15, applicant believes that the language identified by the Examiner has been deleted from the claims. As a result, applicant believes that claims 14 and 15 are definite to one skilled in the art.

In view of the present amendment and the foregoing remarks, therefore, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

- ☐ - a terminal disclaimer
- ☐ - a 37 CFR 1.132 Declaration
- ☐ - a new or amended Abstract of the Disclosure
- ☐ - a Replacement Sheet for Figure of the drawings
- ☐ - a Substitute Specification and a marked-up copy of the originally-filed specification
- ☐ - a verified English translation of foreign priority document
- ☒ - a translation of Swedish Application 9900 674-4 filed on February 25, 1999